

Remarks

This is further to Applicants' amendments and remarks filed on December 7, 2005, which are fully incorporated herein.

Claims 24-35 are pending in this application. Claims 24, 29 and 31 are amended to recite, in part, that the formulation is a direct blend of thalidomide and carrier which blend is filled within capsules. Support for these amendments can be found, for example, on page 12, lines 26-30 and in Sections 4.2.2 and 4.2.4 on page 13 of the specification.

In addition, claims 28, 29, and 35 are amended to more precisely recite the claimed invention. Support for these amendments can be found, for example, on page 11, lines 12-18 of the specification. No new matter has been added.

I. Statement of Substance of Interview

Applicants wish to thank Supervisory Examiner Low and Examiner Roberts for the courtesy they extended to attorneys for Applicants and Dr. McCarty during a personal interview held on December 15, 2005. A brief summary of the interview follows and is supplemental to the interview summary record dated December 15, 2005.

The participants at the interview were: Supervisory Examiner Christopher Low and Examiner Lezah Roberts; Mr. John McCarty, a co-inventor of this application who has extensive experience in the field of pharmaceutical formulations; and Mr. Richard T. Girards, Jr., Mr. Anthony M. Insogna and Mr. Hoon Choi, attorneys for Applicants.

During the interview, all of the rejections raised in the Office Action of August 11, 2005 were discussed. Further, Mr. McCarty addressed the difficulties associated with formulating a new dosage form having a greater amount of active ingredient in a smaller capsule but with the same or better bioavailability to that of the FDA-approved product. Mr. McCarty emphasized that such difficulties are especially true with respect to a drug that has a low water solubility such as thalidomide.

The Examiners suggested certain claim amendments to address patentably distinct features of the invention discussed during the interview. Applicants were invited to submit a supplemental response providing comments on benefits of the formulation, for example, with respect to the manufacturing.

In addition, Applicants brought to the Examiners' attention the names of other thalidomide formulations that may exist, and other formulations known to Applicants, which may or may not be prior art. Applicants discussed a manner in which this information could be made of record. In particular, Applicants and the Examiners went

over a series of documents that disclose the formulations or names thereof and agreed that a statement by Applicants, along with a form "List of References Cited by Applicant," would be appropriate. Again, Applicants reiterate that such disclosure is not an admission that any formulation or designation thereof is prior art. However, for the sake of full disclosure and in an abundance of caution, such is found in an accompanying Information Disclosure Statement.

II. The Claimed Capsule Formulation

As presented by Applicants during the interview, and further to Applicants' response dated December 7, 2005, creating the claimed thalidomide formulations presented various challenges. Such challenges included the poor flow characteristics of thalidomide and "containment" issues, *e.g.*, potential health issues created by thalidomide powder or particulates that may be airborne during the manufacture, given that thalidomide is a well-known teratogen.

The claimed thalidomide formulations address such concerns, for example, in that the formulations need not be subject to roller compaction. The avoidance of roller-compacted product is beneficial because it reduces or avoids containment issues. Similarly, the claimed formulations address the size and bioavailability issues discussed in Applicants' response of December 7, 2005. Indeed, Applicants invented and have claimed a formulation of specific amounts of thalidomide and specific amounts of carrier loaded into a specific capsule size as a direct blend. The direct blend formulation as claimed uses a smaller capsule size, but holds a higher amount of active agent while retaining bioavailability comparable to the old formulation and without the need for roller compaction. Thus, Applicants respectfully submit that the claimed thalidomide formulations are novel and non-obvious.

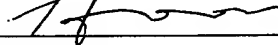
Conclusion

For the reasons discussed above as well as in the response filed December 7, 2005, Applicants respectfully submit that the pending claims are allowable, and thus request that the rejection of the claims be withdrawn.

No fee or extension of terms is believed due for the submission of this paper.
If any fees are required for the submission of this paper, or to avoid abandonment of this application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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